IN THE UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

In re KUGEL MESH HERNIA PATCH PRODUCTS LIABILITY LITIGATION	§	
THIS DOCUMENT RELATES TO:	§	**MDL Docket No. 07-1842-ML**
BYNUM, C. A. No.: 1:07-01873	§	
BETSY L. BYNUM,	§	
Plaintiff,	§	
VS.	§	
DAVOL, INC., and C. R. BARD, INC.,	§	
	§	**DEMAND FOR JURY TRIAL**
Defendants.	§	

PLAINTIFF'S FIRST AMENDED COMPLAINT

Plaintiff, BETSY L. BYNUM, by and through her attorneys, brings this action alleging the following, upon information and belief:

NATURE OF THE ACTION

1. Plaintiff brings this action against C. R. BARD, INC. (hereinafter "BARD") and its wholly owned subsidiary, DAVOL, INC., (hereinafter "DAVOL"), for their sale and distribution of defective hernia patches sold under the product names, Kugel® Hernia Patch, Bard® Kugel® Hernia Patch, and Bard® Composix® Kugel® Hernia Patch, (hereinafter "Kugel Patch"). The Defendants' defective product was surgically implanted into the body of the Plaintiff. The Kugel Patch presents, and will continue to present, a

substantial risk of injury or death to the Plaintiff. As a result, Plaintiff has been injured and will need continual and ongoing medical monitoring.

PARTIES

2. Plaintiff, BETSY L. BYNUM (hereinafter "Plaintiff") is an individual citizen and resident of the County of Gaston, State of North Carolina. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body. The Kugel Patch was later removed.

3. Defendant, DAVOL, INC., (hereinafter "DAVOL") is and was a wholly owned subsidiary of C. R. BARD, INC., with its principal place of business at 100 Sockanosset Crossroads, P.O. Box 8500, Cranston, Rhode Island, 02920, County of Providence. DAVOL has a registered agent in Rhode Island at CT Corporation System, 10 Weybosset Street, Providence, Rhode Island 02903. At all times relevant, DAVOL was a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business for manufacturing hernia surgical repair products in Cranston, Rhode Island. DAVOL designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the States of North Carolina, Rhode Island and Texas.

4. Defendant, C. R. BARD, INC., (hereinafter "BARD") is a New Jersey corporation with its principal office and place of business at 730 Central Avenue, Murray Hill, New Jersey, 07974, County of Union, and at all times relevant designed, manufactured, tested,

analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the States of North Carolina, Rhode Island and Texas.

JURISDICTION AND VENUE

5. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. §1332(a). Plaintiff and no Defendant is a citizen of the same state as Plaintiff and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

6. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(c) because Defendants are corporations. A corporation is deemed to reside in any judicial district where its contacts would be sufficient to subject it to personal jurisdiction at the time the action is commenced. DAVOL and BARD distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners at all times relevant and including the day this action is commenced, certain hernia surgical repair products to be surgically implanted in patients in the State of Texas, and more particularly within the jurisdictional boundaries of the United States District Court for the Southern District of Texas.

GENERAL ALLEGATIONS

7. Plaintiff's action involves patches containing a hard "memory recoil ring" (or "PET coil ring") that surrounds the mesh, first manufactured by Surgical Sense, Inc., starting in or around 1996, acquired by Defendants in 2000, and then manufactured by Defendants

between 2001 and March 2006. These Kugel Patches were sold by Defendants for implantation in patients in the course of hernia repair surgery.

8. A hernia occurs when the stomach muscles are too weak to contain the intestines, and as a result, a rupture occurs in the muscle wall which allows the intestines to protrude. The Kugel Patch was designed to treat ventral hernias caused by the thinning or stretching of scar tissue that forms after surgery.

9. The Kugel Mesh line of products was first manufactured by Surgical Sense, Inc., starting in or around 1996. In January of 2000, BARD acquired the assets and Kugel Patch product line of Surgical Sense, Inc. Shortly thereafter, in 2001, BARD introduced the Kugel Patch through its subsidiary, DAVOL. The Kugel Patches manufactured by Surgical Sense, Inc., and the patches manufactured by Defendants, were approved for sale by the U. S. Food and Drug Administration, hereinafter "FDA," under 510(k) Premarket Notification Submissions.

10. The Kugel Patch, invented by Robert D. Kugel, M. D., is a polypropylene mesh prosthetic device developed to repair ventral hernias, or hernias of the abdominal region. The Kugel Patch is inserted behind the hernia defect in the abdomen through a small incision. In order to fit through the small incision the mesh is folded in half. Once inside the abdomen the mesh re-deploys as a result of a hard "memory recoil ring" (or "PET coil ring") that surrounds the mesh.

11. Due to defects in the design and manufacturing of the Kugel Patch, the "memory recoil ring" that opens the patch can break under the stress of placement of the product in the intra-abdominal space. Once the memory recoil ring has broken, it can later come loose

and cause serious injuries as it travels through the body. These injuries include: intestinal perforations; ring migration through the abdominal wall; abscesses; bowel obstruction and sepsis; and chronic intestinal fistulae (abnormal connections or passageways between the intestines and other organs).

12. The Kugel Patches present and constitute an unreasonable risk of danger and injury in the following respects:

a. the memory recoil ring of the Kugel Patch is likely to malfunction after being implanted;

b. the Kugel Patch was not properly manufactured;

c. the Kugel Patch was defectively designed;

d. the Kugel Patch did not perform as safely as an ordinary consumer/patient would expect;

e. the Kugel Patch was inadequate or insufficient to maintain its integrity during normal use after implantation in the consumer/patient; and

f. such further and additional defects as discovery and the evidence reveal.

13. As a result of this dangerous and defective condition, and the numerous serious injuries that resulted, the FDA issued the first Class 1 Recall of various lots of the Kugel Patches on December 22, 2005. The Class 1 Recall was expanded in subsequent recalls on March 31, 2006, and January 24, 2007. A Class 1 Recall is the highest level of recall available to the FDA. It is issued when the FDA believes a medical product is dangerous or defective and predictably could cause serious health problems or death.

14. The products that are affected by the recall were distributed to customers and implanted in patients worldwide. As of March 2006, roughly 75,000 Kugel Patches had been sold, Upon information and belief, the vast majority of the patches which have been implanted are currently still inside patients residing in the United States. From January 2000 until March 2006, Kugel Patches were sold by Defendants under Items Numbers or Product Codes; 10-101, 10-102, 10-103, 10-104, 10-105, 0010101, 0010102, 0010103, 0010104, 0010105, 0010201, 0010202, 0010203, 0010204, 0010205, 0010206, 0010207, 0010208, and 0010209. Although not all of these Kugel Patches are listed in the FDA's Class 1 Recall, they all have the defective "memory recoil ring."

15. At all times herein mentioned, Defendants knew, or in the exercise of reasonable care should have known, that the aforesaid products were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, were not suitable for the purpose they were intended and were unreasonably likely to injure the products' users.

16. Defendants' Kugel Patches are defective because they possess the potential for breakage or malfunction of the memory recoil ring and, as a result, are subject to risk of resulting injury.

17. Defendants did not timely apprise the public and physicians of the defect in their Kugel Patches, despite Defendants' knowledge that memory recoil rings had failed due to the described defects. Defendants' concealment of a known defect from Plaintiff tolls the applicable statute of limitation. Plaintiff could not have discovered the existence of the

defect in the Kugel Patch implanted in her until at least December 22, 2005, when Defendants first provided notice of the recall.

18. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

19. As a direct and proximate cause of Defendants' conduct and the recalled Kugel Patches, Plaintiff has suffered injuries and will require continual medical monitoring and care. Accordingly, Plaintiff will incur future medical costs related to the recalled Kugel Patches.

PLAINTIFF'S EXPERIENCE

20. Plaintiff underwent a hernia repair surgical procedure on July 30, 2003, at Gaston Memorial Hospital in Gastonia, North Carolina, and during the course thereof, her physician, Sandra B. Schultz, M. D., implanted a Kugel Patch into her body.

21. The Kugel Patch implanted in Plaintiff was designed, manufactured, sold and distributed by Defendants, and was intended to be used by surgeons for hernia repair surgeries. Defendants represented these Kugel Patches to be appropriate and suitable products for such purposes.

22. The Kugel Patch inserted in Plaintiff's body became infected, causing her severe pain and suffering and mental anguish. After less invasive methods failed to resolve the persistent infection, the Kugel Patch was removed on June 24, 2004.

23. As a direct and proximate result of Defendants' defective design, manufacture, function and/or inadequate warnings regarding the Kugel Patch, Plaintiff sustained, and will continue to sustain, injuries and damages.

COUNT I

(Unfair And Deceptive Trade Practices)

24. Plaintiff alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

25. At all times relevant, Defendants were engaged in the design, manufacturing, assembling, distributing, conveying and/or selling of the Kugel Patch in their ordinary course of business. Defendants designed, manufactured, assembled and sold the devices to hospitals and physicians, knowing that they would be thereby sold to patients who needed hernia repair surgery, including Plaintiff.

26. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of the Kugel Patches.

27. Plaintiff is a consumer of the defective product and was injured by Defendants' deceptive and unfair acts.

28. Had the Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Kugel Patch, would not have incurred related medical costs and would not continue to incur these costs.

29. Defendants' representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts or practices in violation of the consumer protection statutes of one or more of the States of Rhode

Island, Texas, the States where the Kugel Mesh was implanted or removed, or the States of residence of the Plaintiff and Defendants.

30. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for the Kugel Patch and/or for the costs of removing and/or replacing the Kugel Patch that he would not have paid had Defendants not engaged in unfair and deceptive conduct.

31. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The purpose of that conduct, directed at patients, physicians and consumers, was to create demand for and to sell the Kugel Patches. Each aspect of Defendants' conduct combined to artificially create sales of the Kugel Patches.

32. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has incurred and will likely continue to incur medical costs relating to the Kugel Patch, including medical monitoring and/or other hospital costs, in an amount to be proven at trial.

33. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff is entitled to injunctive relief in the form of a court supervised medical monitoring program, punitive damages, attorneys fees, and costs of suit.

34. Medical monitoring is medically reasonable and necessary in order to provide for the early detection and prevention of irreparable harm, severe and debilitating injuries and death. In the absence of such relief, Plaintiff might not receive prompt medical care that could prolong her productive life, increase prospects for improvement and to minimize disability.

COUNT II

Negligence

35. Plaintiff alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

36. Defendants DAVOL and BARD were negligent to Plaintiff in the following respects:

37. DAVOL and BARD at all times mentioned had a duty to properly manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for use the Kugel Patch.

38. DAVOL and BARD at all times mentioned knew or in the exercise of reasonable care should have known that the Kugel Patches were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure the Kugel Patch's users.

39. DAVOL and BARD so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Kugel Patch, that they were dangerous and unsafe for the use and purpose for which it was intended.

40. DAVOL and BARD were aware of the probable consequences of the Kugel Patch. DAVOL and BARD knew or should have known that the Kugel Patch would cause serious injury; they failed to disclose the known or knowable risks associated with the Kugel Patch. DAVOL and BARD willfully and deliberately failed to avoid those consequences, and in doing so, DAVOL and BARD acted in conscious disregard for the safety of Plaintiff.

41. Defendants DAVOL and BARD owed a duty to Plaintiff to adequately warn Plaintiff and Plaintiff's treating physicians of the risks of breakage, separation, tearing and splitting associated with the Kugel Patch and the resulting harm and risk it would cause patients.

42. Defendants DAVOL and BARD breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Kugel Patch.

43. As a direct and proximate result of the duties breached, the Kugel Patch used in the Plaintiff's hernia repair surgery failed, resulting in Plaintiff suffering pain and harm.

44. As a direct and proximate result of DAVOL's and BARD's negligence, Plaintiff has suffered injuries and damages.

45. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Kugel Patch after obtaining knowledge that they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

COUNT III

Strict Liability

46. Plaintiff alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

47. Defendants DAVOL and BARD are strictly liable to Plaintiff in the following respects:

48. DAVOL and BARD designed, manufactured, assembled, distributed, conveyed and/or sold the Kugel Patch for hernia repair surgery.

49. The Kugel Patches subject to the Class I Recall were defective because they failed to perform safely and effectively for the purpose they were originally designed. Plaintiff's Kugel Patch was a Class I recalled device that failed while in Plaintiff's body, causing Plaintiff to develop serious physical complications which may require or required subsequent, painful and unnecessary surgical removal of her Kugel Patch.

50. At all times mentioned, the Kugel Patch was substantially in the same condition as when it left the possession of DAVOL.

51. The Kugel Patch implanted into Plaintiff was being used in a manner reasonably anticipated at the time it was implanted in her by her surgeon.

52. The Kugel Patches, like the one found in Plaintiff, at the time they left the possession of DAVOL and BARD were inherently dangerous for their intended use and were unreasonably dangerous products which presented and constituted an unreasonable risk of danger and injury to Plaintiff as follows:

a. The Kugel Patch was sold in a defective condition by design and manufacture;

b. The Kugel Patch as designed and manufactured was unsafe to Plaintiff;

c. The Kugel Patch as designed and manufactured was unreasonably dangerous to Plaintiff;

d. The Kugel Patch did not perform safely as an ordinary consumer/patient, like Plaintiff, would expect;

e. The Kugel Patch as designed and manufactured was unsafe for its intended use;

f. DAVOL and BARD failed to warn the end user about the dangers and risks of the product;

g. DAVOL and BARD knew the component parts of the Kugel Patch as implemented through design and/or manufacture could cause injury to the end user;

h. Failing to implement an adequate, safe and effective "memory recoil ring" and/or its interaction with the mesh of the Kugel Patch to withstand the foreseeable stresses they would be subject to within the intra-abdominal space;

i. Failing to avoid migration of the Kugel Patch and/or its components from the initial site of the hernia repair surgery;

j. Any other acts or failures to act by DAVOL or BARD regarding the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and/or sale of Kugel Patches for hernia repair surgery as will be learned during discovery.

53. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Kugel Patch after obtaining knowledge that they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

COUNT IV

Intentional Infliction of Emotional Distress

54. Plaintiff alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

55. Defendants DAVOL and BARD are liable to Plaintiff for the intentional infliction of emotional distress in the following respects:

56. Plaintiff suffered severe emotional distress, which was a result of DAVOL's and BARD's extreme, outrageous, intentional, willful, and reckless conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or sale of the Kugel Patch for hernia repair surgery.

57. Plaintiff suffered severe emotional distress, which was as a result of DAVOL's and BARD's extreme, outrageous, intentional, willful, and reckless conduct in failing to adequately and safely design and construct an effective and safe Kugel Patch for hernia repair surgery, in complete and reckless disregard for the safety of Plaintiff.

58. Therefore, DAVOL and BARD are liable to Plaintiff.

59. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Kugel Patch after obtaining knowledge that they were failing and not performing as represented and intended showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

COUNT V

Breach of Implied Warranty

60. Plaintiff alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

61. Defendants DAVOL and BARD are liable to Plaintiff for their breach of implied warranty in the following respects:

62. DAVOL and BARD sold the Kugel Patch which was implanted in the Plaintiff. DAVOL and BARD impliedly warranted to Plaintiff, Plaintiff's physicians and healthcare providers, that the Kugel Patch was of merchantable quality and safe for the use for which it was intended.

63. DAVOL and BARD knew or should have known that the Kugel Patch at the time of sale was intended to be used for the purpose of surgically implanting them into the body for hernia repair.

64. Plaintiff, Plaintiff's physicians and health care providers reasonably relied on DAVOL's and BARD's judgment, indications and statements that the Kugel Patch was fit for such use.

65. When the Kugel Patch was distributed into the stream of commerce and sold by DAVOL and BARD, it was unsafe for its intended use, and not of merchantable quality, as warranted by DAVOL and BARD, in that it had very dangerous propensities when used as intended and implanted into a patient's body where it could cause serious injury of harm or death to the end user.

66. Plaintiff suffered such injuries and damages as a result of DAVOL's and BARD's conduct and actions.

COUNT VI

Failure to Warn

67. Plaintiff alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

68. In the course of business, DAVOL and BARD designed, manufactured and sold the Kugel Patch to Gaston Memorial Hospital for hernia repair surgeries.

69. At the time of the design, manufacture and sale of the Kugel Patch, and more specifically at the time Plaintiff received the Kugel Patch, they were defective and unreasonably dangerous when put to their intended and reasonably anticipated use. Further, the Kugel Patches were not accompanied by proper warnings regarding significant adverse consequences associated with the Kugel Patch.

70. BARD and DAVOL failed to provide any warnings, labels or instructions of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the products involved significant dangers not readily obvious to the ordinary user of the products. BARD and DAVOL failed to warn of the known or knowable injuries associated with malfunction of the Kugel Patch, including but not limited to rupture of the Kugel Patch and severe peritonitis and infection which would require subsequent surgical procedures and could result in severe injuries.

71. The dangerous and defective conditions in the Kugel Patches existed at the time they were delivered by the manufacturer to the distributor. At the time Plaintiff had hernia repair surgery, the Kugel Patch was in the same condition as when manufactured, distributed and sold.

72. Plaintiff did not know at the time of use of the Kugel Patch, nor at any time prior thereto, of the existence of the defects in the Kugel Patches.

73. Plaintiff suffered the aforementioned injuries and damages as a direct result of DAVOL's and BARD's failure to warn.

74. The conduct of DAVOL and BARD in continuing to market, promote, sell and distribute the Kugel Patch after obtaining knowledge that the products were failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter DAVOL, BARD and others from similar conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

a. For all damages available to Plaintiff under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, and disfigurement;

b. For an Order establishing a medical monitoring program, funded by Defendants, to provide medical testing, screening, services, research and education and a medical/legal registry to ensure that he receives prompt and proper medical treatment;

c. For punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing;

d. For all applicable statutory damages under the consumer protection statutes of one or more of the States of Rhode Island, Texas, the States where the Kugel Mesh was implanted or removed, or the States of residence of the Plaintiff and Defendants;

e. For an award of attorneys' fees and costs;

f. For prejudgment interest and the costs of suit; and

g. For such other relief as this court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury in this case.

Dated: This 12th day of January, 2008.

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CERTIFICATION

I hereby certify that on this 12th day of January, 2008, that a true copy of the foregoing Plaintiff's First Amended Complaint has been filed electronically and that it is available for viewing and downloading from the ECF system. I also certify that a true copy of this document was also mailed or electronically mailed to the following:

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